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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,188	08/09/2001	Jean Ackermann	20739	4231

151 7590 05/05/2004

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
340 KINGSLAND STREET
NUTLEY, NJ 07110

EXAMINER	
ROBINSON, BINTA M	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,188	ACKERMANN ET AL.	
	Examiner	Art Unit	
	Binta M. Robinson	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,6-17,21,22,24-30,34-45 and 63-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-17,21,22,24-30,34-45 and 63-98* is/are rejected.

7)☒ Claim(s) *93* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claims 1, 3-4, 6-17, 21-22, 24-30, 34-45, 63-98 are now pending.

The examiner appreciates the applicant's narrowing of the claims to the elected subject matter of Group IV which reads on the compound of formula I where V is –Ch2-, -CH=CH- or alkynyl, A1-A4 do not contain a carbon ring, and all other variables are as recited, a pharmaceutical composition, and a process of preparing compounds of formula I. However, the claims are not allowable as is, because new rejections have been found.

(new rejections)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 4, 6, 7, 8-17, 21, 22, 24-30, 34-45, 63-92, 94, 95, 96, 97, 98 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16-22 of copending Application No. 2003/0186984 A1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent application claims a genus that encompasses the subgenus of instant compounds and pharmaceutical compositions containing.

Application No. 2003/0186984 A1 et. al. teaches the instant compound as shown in Formula I, wherein U is O or a lone pair, V is –CH=CH- or alkynyl, m and n independently from each other are 0 to 7 and m+n is 0 to 7, o is 0 , A1 is hydrogen, lower-alkyl, hydroxy-lower-alkyl, or lower alkenyl, A2 is lower-alkyl, cycloalkyl, cyclylalkyl-lower-alkyl, or lower-alkenyl, optionally substituted by R1, A3 and A4 independently from each other are hydrogen or lower-alkyl or A5 is hydrogen, lower-alkyl, or lower-alkenyl, A6 is pyridinyl, pyridazinyl, pyrimidinyl or pyrazinyl, r1 is hydroxy, hydroxy-lower-alkyl, lower-alkoxy, loweralkoxy carbonyl, N(R3R4) or thio-loweralkoxy, R3 and R4 independently from each other are hydrogen or lower-alkyl. At column 32, see the compound of formula I and the radicals defined. The difference between the prior art compound and the instantly claimed compounds and the pharmaceutical compositions containing them is that the instant compounds are a subgenus of the genus of Application No. 2003/0186984 compounds. It would have been obvious to one of ordinary skill in the art to select various known radicals within a genus to prepare structurally similar compounds. For instance, see claim 32, where a disclosed species is exemplified. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 3, 37, 39, 41, 42, 43, 44, 66, 68, 69, 70, 71, 73, -75, 77, 78, 82, 86, 87-88, 90-92, 95, 97 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, line 8, page 3 and all other occurrences throughout claims 3, 37, 39, 41, 42, 43, 44, 66, 68, 69, 70, 71, 73, -75, 77, 78, 82, 86, 87-88, 90-92, 95, 97, the phrase "and pharmaceutically acceptable esters of the compounds of formula I" is ambiguous. Esters of the compounds of formula I are not the same species as the compound of formula I. What Esters of the compounds of formula I is the applicant claiming? Additionally, these claims are compound claims simultaneously making a claim to one compound and then more than one compound. However, a compound claim can only claim one compound at a time, because a compound can only consist of one compound at a time. However, a mixture or composition consists of at least two compounds. Is the applicant claiming a composition or a compound in these claims?

B. Claim 1 recites the limitation "V is O or S" in line 9, page 2 of the amendment filed 2/20/04. There is insufficient antecedent basis for this limitation in the claim.

Claims 93 is objected to for being based on rejected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

BMR

JOSEPH K. McKANE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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ROBINSON, BINTA M	

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DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of Ackermann et al.

Serial No.:	09/925,188	Group:	1623
Filed:	August 9, 2001	Examiner:	B. M. Robinson

For: 2,3-OXIDOSQUALENE-LANOSTEROL CYCLASE INHIBITORS

SUPPLEMENTAL AMENDMENT

Nutley, New Jersey 07110
February 18, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir/Madam:

This Supplemental Amendment is being filed in response to the Communication dated January 30, 2004. A response to this Communication is due February 29, 2004. Accordingly, this response is timely filed, and no additional fee for extension of time is required.

Please amend the application as follows.

Amendments to the Claims are reflected in the listing of claims that begins on page 2 of this paper.

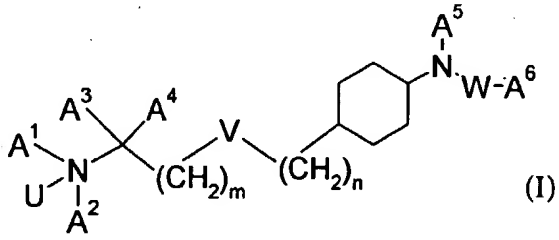
Remarks begin on page 12 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently Amended) A compound selected from the group consisting of compounds of formula (I)



(I)

wherein

U	is O or a lone pair;
V	is ~~O, S,~~ $-CH_2-$, -CH=CH-, or -C≡C-;
W	is CO, COO, $CONR^1$, CSO, $CSNR^1$, SO_2, or SO_2NR^1;
m and n	are each integers from 0 to 7, with the provisos that m+n is 0 to 7 and m is not 0 when V is O or S;
A^1	is H, lower-alkyl, hydroxy-lower-alkyl, or lower-alkenyl; and
A^2	is lower-alkyl, cycloalkyl, cycloalkyl-lower-alkyl, or lower-alkenyl, optionally substituted by R^2~~, or~~
~~A^1 and A^2~~	~~bond together to form $-A^1-A^2-$, wherein $-A^1-A^2-$ is lower-alkylene or lower-alkenylene, optionally substituted by R^2, in which one $-CH_2-$ group of $-A^1-A^2-$ is optionally replaced by NR^3, S, or O;~~
A^3 and A^4	are each hydrogen or lower-alkyl~~, or~~
~~A^3 and A^4~~	~~bond together to form $-A^3-A^4-$, wherein $-A^3-A^4-$ is $-(CH_2)_{2-5}-$ optionally mono- or multiply-substituted by lower-alkyl;~~
A^5	is H, lower-alkyl, lower-alkenyl, or aryl-lower-alkyl;
A^6	is lower-alkyl, cycloalkyl, aryl, aryl-lower-alkyl, heteroaryl, heteroaryl-lower-alkyl, lower-alkoxy-carbonyl-lower-alkyl;

R^2 is hydroxy, hydroxy-lower-alkyl, lower-alkoxy, lower-alkoxycarbonyl, $N(R^4,R^5)$, or thio-lower-alkoxy; and

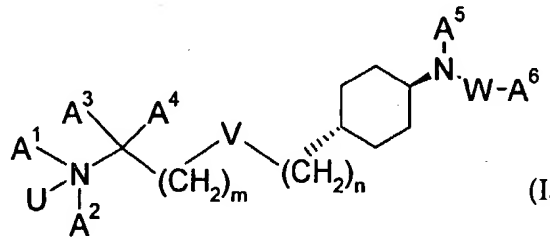
R^1, R^3, R^4 and R^5 independently from each other are hydrogen or lower-alkyl; ~~and when A^1 is not bonded to A^2 and A^3 is not bonded to A^4, A^1 and A^3 optionally bond together to form A^1-A^3-, wherein A^1-A^3- is lower alkylene or lower-alkenylene, optionally substituted by R^2, in which one CH_2 group of A^1-A^3- is optionally replaced by NR^3, S, or O;~~

pharmaceutically acceptable salts of the compounds of formula (I), and

pharmaceutically acceptable esters of the compounds of formula (I).

2. (Canceled)

3. (Original) The compound according to claim 1, selected from the group consisting of compounds of formula (Ia):



(Ia)

wherein U, V, W, m, n, A^1, A^2, A^3, A^4, A^5 and A^6 are as defined in claim 1;

pharmaceutically acceptable salts of the compounds of formula (Ia); and

pharmaceutically acceptable esters of the compounds of formula (Ia).

4. (Original) The compound according to claim 1, wherein U is a lone pair.

5. (Canceled)

6. (Original) The compound according to claim 4, wherein V is $-CH_2-$.

7. (Original) The compound according to claim 4, wherein V is -C=C-.

8. (Original) The compound according to claim 4, wherein V is -C≡C-.

9. (Original) The compound according to claim 4, wherein W is CO, COO, $CONR^1$, $CSNR^1$, SO_2 or SO_2NR^1 and R^1 is hydrogen.

10. (Original) The compound according to claim 9, wherein W is COO or SO_2.

11. (Original) The compound according to claim 10, wherein n is 0.

12. (Original) The compound according to claim 10, wherein n is 1.

13. (Original) The compound according to claim 10, wherein m is 1 to 6.

14. (Original) The compound according to claims 10, wherein m is 0 and V is -C=C- or -C≡C-.

15. (Original) The compound according to claim 10, wherein A^1 is H, methyl, ethyl, isopropyl, 2-hydroxy-ethyl, or 2-propenyl.

16. (Original) The compound according to claim 10, wherein A^2 is lower-alkyl, cycloalkyl-lower-alkyl, or lower-alkenyl, optionally substituted with R2, wherein R2 is hydroxy, methoxy, or ethoxycarbonyl.

17. (Original) The compound according to claim 16, wherein A^2 is methyl, ethyl, 2-hydroxy-ethyl, 2-propenyl, propyl or isopropyl.

Claims 18-20. (Canceled)

21. (Original) The compound according to claim 10, wherein A^3 is hydrogen.

22. (Original) The compound according to claim 10, wherein A^4 is hydrogen.

23. (Canceled)

24. (Original) The compound according to claim 10, wherein A^5 is H, lower-alkyl, lower-alkenyl, or benzyl optionally substituted with halogen.

25. (Original) The compounds according to claim 24, wherein A^5 is methyl or ethyl.

26. (Original) The compound according to claim 25, wherein A^6 is lower-alkyl, cycloalkyl, phenyl, naphthyl, phenyl-lower-alkyl, pyridyl, indolyl, indolinyl, thienyl, thienyl-methylene, furyl-methylene, benzodioxyl, chinolyl, isoxazolyl, or imidazolyl, optionally substituted by one or more substituents selected from the group consisting of lower-alkyl, lower-alkoxy, lower-alkylcarbonyl, lower-alkoxycarbonyl, fluorine, chlorine, bromine, CN, CF_3, NO_2, or $N(R^6,R^7)$, wherein R^6 and R^7 independently from each other are hydrogen or lower-alkyl.

27. (Original) The compound according to claim 26, wherein A^6 is phenyl optionally substituted by one or more substituents selected from the group consisting of fluorine, chlorine, bromine, and CF_3.

28. (Original) The compound according to claim 27, wherein A^6 is 4-chloro-phenyl, 4-bromo-phenyl, or 4-trifluoromethyl-phenyl.

29. (Original) The compound according to claim 28, wherein A^1 is H, lower alkyl or hydroxy-lower alkyl and A^2 is lower alkyl, hydroxy-lower alkyl or lower alkenyl.

30. (Original) The compound according to claim 29, wherein A^3 and A^4 are hydrogen.

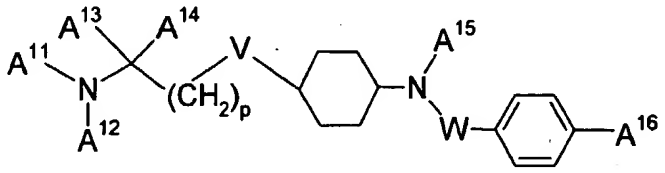
Claims 31-33. (Canceled)

34. (Original) The compound according to claim 30, wherein V is $-CH_2-$.

35. (Original) The compound according to claim 30, wherein V is -C=C-.

36. (Original) The compound according to claim 30, wherein V is -C≡C-.

37. (Currently amended) A compound selected from the group consisting of compounds of formula (Ib):



(Ib)

wherein

V is ~~O, S,~~ $-CH_2-$, -CH=CH-, or -C≡C-;

W is COO or SO_2;

p is an integer from 0 to 7, with the proviso that p is not 0 when V is O or S;

A^{11} is H, lower-alkyl, or hydroxy-lower-alkyl; ~~and~~

A^{12} is lower-alkyl, hydroxy-lower alkyl, or lower-alkenyl~~, or~~

~~A^{11} and A^{12} bond together to form A^{11}-A^{12}, wherein A^{11}-A^{12} is lower alkylene~~;

A^{13} and A^{14} are each hydrogen ~~or bond together to form A^{13}-A^{14}, wherein A^{13}-A^{14} is $(CH_2)_{2-5}$.~~;

A^{15} is lower-alkyl; and

A^{16} is halogen or trifluoromethyl;

pharmaceutically acceptable salts of the compounds of formula (Ib), and

pharmaceutically acceptable esters of the compounds of formula(Ib).

38. (Previously amended) The compound according to claim 37, wherein A^{11} is H, lower-alkyl, or hydroxy-lower-alkyl and A^{12} is lower-alkyl, hydroxy-lower alkyl, or lower-alkenyl.

39. (Original) The compound according to claim 38, selected from the group consisting of trans-N-{4-[2-(1-dimethylamino-cyclopropyl)-ethoxy]-cyclohexyl}-N-methyl-4-trifluoromethyl-benzenesulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

40. (Original) The compound according to claim 37, whereon A^{13} and A^{14} are hydrogen.

41. (Original) The compound according to claim 40, selected from the group consisting of trans-4-bromo-N-methyl-N-[4-(2-piperidin-1-yl-ethoxy)-cyclohexyl]-benzenesulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

42. (Original) The compound according to claim 40, selected from the group consisting of trans-methyl-[4-(4-piperidin-1-yl-butyl)-cyclohexyl]-carbamic acid 4-bromo-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

43. (Original) The compound according to claim 40, selected from the group consisting of trans-N-methyl-N-[4-(4-piperidin-1-yl-butyl)-cyclohexyl]-4-trifluoromethyl-benzenesulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

44. (Original) The compound according to claim 40, selected from the group consisting of trans-methyl-[4-(5-piperidin-1-yl-pentyl)-cyclohexyl]-carbamic acid 4-cloro-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

45. (Original) The compound according to claim 40, wherein A^{11} is H, lower-alkyl, or hydroxy-lower-alkyl and A^{12} is lower-alkyl, hydroxy-lower alkyl, or lower-alkenyl.

Claims 46-62. (Canceled).

63. (Original) The compound according to claim 45, wherein V is $-CH_2-$.

64. (Original) The compound according to claim 63, wherein W is COO.

65. (Original) The compound according to claim 64, wherein A^{11} is H.

66. (Original) The compound according to claim 65, selected from the group consisting of trans-methyl-[4-(5-methylamino-pentyl)-cyclohexyl]-carbamic acid 4-trifluoromethyl-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

67. (Original) The compound according to claim 64, wherein A^{11} is methyl.

68. (Original) The compound according to claim 67, selected from the group consisting of trans-{4-[5-(allyl-methyl-amino)-pentyl]-cyclohexyl}-methyl-carbamic acid 4-trifluoromethyl-

phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

69. (Original) The compound according to claim 67, selected from the group consisting of trans-{4-[5-(allyl-methyl-amino)-pentyl]-cyclohexyl}-methyl-carbamic acid 4-bromo-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

70. (Original) The compound according to claim 67, selected from the group consisting of trans-{4-[5-(allyl-methyl-amino)-pentyl]-cyclohexyl}-methyl-carbamic acid 4-chloro-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

71. (Original) The compound according to claim 67, selected from the group consisting of trans-{4-[4-(allyl-methyl-amino)-butyl]-cyclohexyl}-methyl-carbamic acid 4-chloro-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

72. (Original) The compound according to claim 64, wherein A^{11} is ethyl.

73. (Original) The compound according to claim 72, selected from the group consisting of trans-(4-{5-[ethyl-(2-hydroxy-ethyl)-amino]-pentyl}-cyclohexyl)-methyl-carbamic acid 4-trifluoromethyl-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

74. (Original) The compound according to claim 72, selected from the group consisting of trans-(4-{5-[ethyl-(2-hydroxy-ethyl)-amino]-pentyl}-cyclohexyl)-methyl-carbamic acid 4-bromo-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

75. (Original) The compound according to claim 72, selected from the group consisting of trans-(4-{3-[ethyl-(2-hydroxy-ethyl)-amino]-propyl}-cyclohexyl)-methyl-carbamic acid 4-chloro-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

76. (Original) The compound according to claim 63, wherein W is SO_2.

77. (Original) The compound according to claim 76, selected from the group consisting of trans-N-{4-[5-(allyl-methyl-amino)-pentyl]-cyclohexyl}-N-methyl-4-trifluoromethyl-

benzenesulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

78. (Original) The compound according to claim 76, selected from the group consisting of trans-N-(4-{5-[ethyl-(2-hydroxy-ethyl)-amino]-pentyl}-cyclohexyl)-N-methyl-4-trifluoromethyl-benzenesulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

79. (Original) The compound according to claim 45, wherein V is -C=C-.

80. (Original) The compound according to claim 79, wherein W is COO.

81. (Original) The compound according to claim 79, wherein W is SO_2.

82. (Original) The compound according to claim 81, selected from the group consisting of trans-(1E)-N-methyl-N-{4-[3-(methyl-propyl-amino)-propenyl]-cyclohexyl}-4-trifluoromethyl-benzenesulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

83. (Original) The compound according to claim 81, selected from the group consisting of trans-(1E)-N-(4-{3-[ethyl-(2-hydroxy-ethyl)-amino]-propenyl}-cyclohexyl)-N-methyl-4-trifluoromethyl-benzenesulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

84. (Original) The compound according to claim 45, wherein V is -C≡C-.

85. (Original) The compound according to claim 84, wherein W is COO.

86. (Original) The compound according to claim 85, selected from the group consisting of trans-{4-[3-(allyl-methyl-amino)-prop-1-ynyl]-cyclohexyl}-methyl-carbamic acid 4-chloro-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

87. (Original) The compound according to claim 85, selected from the group consisting of trans-(4-{5-[ethyl-(2-hydroxy-ethyl)-amino]-pent-1-ynyl}-cyclohexyl)-methyl-carbamic acid 4-

chloro-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

88. (Original) The compound according to claim 85, selected from the group consisting of trans-methyl-{4-[3-(methyl-propyl-amino)-prop-1-ynyl]-cyclohexyl}-carbamic acid 4-chloro-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

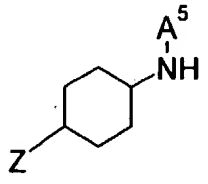
89. (Original) The compound according to claim 84, wherein W is SO_2.

90. (Original) The compound according to claim 89, selected from the group consisting of trans-N-[4-(4-dimethylamino-but-1-ynyl)-cyclohexyl]-N-methyl-4-trifluoromethyl-benzene-sulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

91. (Original) The compound according to claim 89, selected from the group consisting of trans-N-methyl-N-{4-[4-(methyl-propyl-amino)-but-1-ynyl]-cyclohexyl}-4-trifluoromethyl-benzenesulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

92. (Original) The compound according to claim 89, selected from the group consisting of trans-N-(4-{4-[ethyl-(2-hydroxy-ethyl)-amino]-but-1-ynyl}-cyclohexyl)-N-methyl-4-trifluoro-methyl-benzenesulfonamide, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

93. (Original) A process for the manufacture of a compound according to claim 1, comprising reacting a compound of formula (II):



(II)

wherein

A^5 is as defined in claim 1,

Z is a group $(A^1, A^2)N\text{-}C(A^3,A^4)\text{-}(CH_2)_m\text{-}V\text{-}(CH_2)_n$ or $HO\text{-}(CH_2)_n$, wherein A^1, A^2, A^3, A^4, V, m and n are defined as in claim 1,

with ClSO2-A^6, ClCOO-A^6, ClCSO-A^6, OCN-A^6, SCN-A^6, HOOC-A^6, or $ClSO_2NR^1$-A^6, wherein A^6 is as defined in claim 1.

94. (Previously added) A pharmaceutical composition comprising a compound according to claim 1 and at least one of a pharmaceutically acceptable carrier or a pharmaceutically acceptable adjuvant.

95. (Previously added) The compound according to claim 36, selected from the group consisting of trans-methyl-{4-[5-(methyl-propyl-amino)-pent-1-ynyl]-cyclohexyl}-carbamic acid 4-chloro-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

96. (Previously added) A pharmaceutical composition comprising a compound according to claim 95 and at least one of a pharmaceutically acceptable carrier or a pharmaceutically acceptable adjuvant.

97. (Previously added) The compound according to claim 85, selected from the group consisting of trans-methyl-{4-[5-(methyl-propyl-amino)-pent-1-ynyl]-cyclohexyl}-carbamic acid 4-chloro-phenyl ester, pharmaceutically acceptable salts thereof and pharmaceutically acceptable esters thereof.

98. (Previously added) A pharmaceutical composition comprising a compound according to claim 97 and at least one of a pharmaceutically acceptable carrier or a pharmaceutically acceptable adjuvant.

REMARKS

Claims 1-98 were pending in the subject application. Claims 1 and 37 have been amended. Claims 2, 5, 18-20, 23, 31-33, and 46-62 have been canceled without prejudice; and Applicant reserves the right to present these claims (as well as original claims 1 and 37) in a divisional application. Accordingly, claims 1, 3-4, 6-17, 21-22, 24-30, 34-45, and 63-98 remain pending in the subject application.

Claims 1 and 37 have been amended, and claims 2, 5, 18-20, 23, 31-33, and 46-62 have been canceled, to narrow the claims to the restricted subject matter of Group 4. More specifically, claims 1 and 37 have been amended to narrow the claims to compounds where V is– CH_2-, -CH=CH-, or -C≡C-, and A^1-A^4 do not contain a ring. Support for the amendments may be found in the originally filed specification (including the originally filed claims) – more specifically, for example, at paragraphs 27 through 37. No new matter was added. None of the amendments is being introduced for reasons of patentability, nor have any claims been canceled for reasons of patentability.

Interview Summary

Applicants wish to express their gratitude and thanks for the personal interview extended by Examiner Robinson on January 9, 2004. No demonstrations were conducted. All of the claims were discussed generally; and no specific prior art references were discussed. Applicants' representative reiterated the arguments (as set forth in Applicants' prior response) against the Examiner's enablement rejections in Examiner's prior office action, and explained how the various embodiments of Applicants' invention are fully enabled.

The Examiner noted that claims of elected Group 4 were patentable but expressed concern over the burden of fully examining the non-elected subject matter. The Examiner proposed that narrowing the claims to the restricted subject matter of Group 4 would put the case in condition for allowance. While Applicants continue to assert that the MPEP requires full patentability examination of withdrawn claims directed to non-elected inventions where the elected claims are

found to be allowable and the application includes appropriate linking claims, Applicants agreed to narrow the claims to the subject matter of elected Group 4 in order to advance prosecution and to ease the burden on the Examiner. During the interview, Applicants' representative stressed that Applicants reserved the right to present any canceled claims (and the original versions of any amended claims) in divisional applications to be filed in the future.

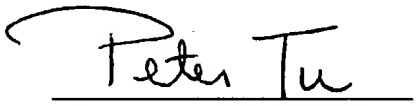
Miscellaneous

In view of the fact that the Examiner has maintained the restriction and election of species requirement, Applicants wish to note on the record that the Examiner has implicitly found that the species not rejoined into the allowable generic claims remaining are patentably distinct from each of the species examined. See MPEP § 808.01(a).

No fee is required in connection with the filing of this Amendment. If any fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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